DEPARTMENT OF HEALTH AND HUMAN SERVICES

93004J

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 20, 2001

Rod D. Van de Graaf, Manager
Van de Graaf Ranches, Inc.
1691 Midvale Road
Sunnyside, Washington 98944

In reply refer to Warning Letter SEA 02-24

WARNING LETTER

Dear Mr. Van de Graaf:

An inspection performed at your medicated feed mill located at 1691 Midvale Road, Sunnyside, Washington, on November 5 through 8, 2001 found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulations, Part 225 (21 CFR 225)]. Such deviations cause medicated feeds being manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found the following deviations:

1. For feeds requiring an approved Mill License for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by an approved official method, at periodic intervals during the calendar year, unless otherwise specified [21 CFR 225.58(b)(1)]. During calendar year 2001, your firm had not performed assays on ration number 1 and ration number 20, which contain the drug component [redacted] contains chlortetracycline/sulfamethazine. The last samples collected for [redacted] was in July 2000 (ration number 20) and December 2000 (ration number 1).

2. Your firm failed to investigate and document out-of tolerance assays performed, in calendar year 2000, as referenced in item #1 above. The December 2000 report for [redacted] for ration number 1 found that the sample contained less than 9.1 grams of chlortetracycline per ton of feed when it reportedly contained 20 grams of chlortetracycline per ton of feed. Also, your firm did not report these failures to meet specifications to FDA's Center for Veterinary Medicine, as required by 21 CFR 510.301.

3. Your firm failed to maintain daily inventory records for category I and category II drugs, which includes the following information:

    - Manufacturers lot number.
    - Quantity of drug on hand at the beginning and end of the workday.
    - Amount of drug used.
    - Number of batches of medicated feed made
    - Records showing an accounting of medication used vs. product produced.

4. Your firm failed to accurately account for the quantity of drug received vs. the quantity of finished product produced. According to your production records for the drug [redacted] your firm used [redacted] pounds. Your receiving records, including drug carried over in inventory from calendar year 2000, showed [redacted] pounds. This was a [redacted] pound discrepancy that could result in sub-potent batch(s) being produced. Your analytical finding from the December 2000 sample tend to confirm that you have produced at least one sub-potent batch.

The above is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Applications under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). This letter constitutes official notification under the law. Based on the result of this inspection, evaluated together with the evidence before FDA when the Medicated Feed Applications were approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our finding and provides you an opportunity to correct the above deficiencies.

Until the CGMP violations have been corrected and the corrections verified by FDA, the Center for Veterinary Medicine would not approve medicated feed applications for your facility.

Your should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Enclosure:
Form FDA 483

Sincerely,

Charles M. Breen
District Director